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Docket No. SPO-121  
Serial No. 10/535,585Remarks

Claims 1-17 were previously pending in the subject application. By this Amendment, claims 6-8 and 14-16 have been amended and new claims 18-24 have been added. No new matter has been added by these amendments. Support for these amendments can be found, for example, in Example 1 (see page 19, line 25 through page 20, line 16) and in previously presented claim 17 and original claims 2-8. Accordingly, claims 1-24 are now before the Examiner for consideration.

The amendments to the claims have been made in an effort to lend greater clarity to the claimed subject matter and to expedite prosecution. The amendments should not be taken to indicate the applicants' agreement with, or acquiescence to, the rejections of record. Favorable consideration of the claims now presented, in view of the remarks and amendments set forth herein, is earnestly solicited.

The applicants have added the units of Daltons ("Da") for the molecular weight to claims 7 and 15, as suggested by the Examiner. Support for this addition can be found in Example 1 in the specification (see page 20, lines 1-3; see Millipore online catalog). The applicants appreciate the Examiner's helpful suggestion.

Claims 6-8 and 14-16 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite. The applicants aver that the claims as currently amended particularly point out and distinctly claim the subject matter of the applicants' invention. Specifically, the applicants submit that the above amendments to claims 6 and 14 have sufficient support in the specification (see page 10, lines 1-8). The applicants appreciate the Examiner's helpful suggestion. Reconsideration and withdrawal of the rejection under 35 U.S.C. §112, second paragraph, is respectfully requested.

Claims 1-3, 6-8, 9-11, and 14-17 have been rejected under 35 U.S.C. §103(a) as being obvious over *Grey et al.* (U.S. Patent No. 5,714,472) in view of McCabe (U.S. Patent No. 6,830,766) and Davis *et al.* (U.S. Patent No. 6,998,259) as evidenced by Fritsche *et al.* (U.S. Patent No. 6,737,076). The applicants respectfully traverse this ground of rejection because the combination of references does not teach or suggest the claimed compositions and methods.

*Grey et al.* teach an enteral formulation comprising a protein source (milk protein hydrolysate), a high oleic acid-containing lipid source including soy oil and lecithin, and

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carbohydrates. However, as the Examiner points out, Gray *et al.* do not disclose several aspects of the claimed invention. Specifically, Gray *et al.* do not mention a protein derived from fermented milk, using palatinose as a carbohydrate, or obtaining the milk protein hydrolysate by an enzymatic hydrolysis of a whey protein isolate (WPI).

McCabe teaches a high protein food composition comprising a polyol as a carbohydrate source and a protein derived from fermented milk. McCabe discloses that a polyol may be used in place of simple sugars in order to provide a slowly metabolizable carbohydrate.

Gray *et al.* and McCabe describe nutritional compositions for completely different purposes. Gray *et al.* teach an enteral formulation for treating intensive care patients and wound healing. McCabe, on the other hand, teaches a high-protein food to be used as an "athletic bar" or "sports bar" to increase muscle mass and provide energy boosts. A person of ordinary skill in the art would not have had any motivation to combine these references, which are targeted at accomplishing very distinct goals.

Additionally, Gray *et al.* teach that it is an advantage of their invention "that nutrient malabsorption is reduced by the absence of whole proteins and by the use of protein hydrolysate, free amino acids and medium chain triglycerides" (see col. 2, lines 56-60). Gray *et al.* go on to further discuss the disadvantages of using whole proteins in their formulation and state that it is more effective to use protein hydrolysates (see col. 8, line 58 through col. 9, line 4). Therefore, it would have been contrary to the purpose and teaching of the Gray patent, and thus counter-intuitive, for one of ordinary skill in the art to use the whole protein derived from fermented milk, as disclosed by McCabe, in the enteral formulation of Gray *et al.*

Furthermore, Gray *et al.* disclose that another advantage of their invention is that the content of carbohydrate is reduced to lessen the risk of hyperglycemia and related problems (see col. 2, lines 51-55). Thus, a person of ordinary skill in the art would not have had motivation to use a polyol, as discussed by McCabe, in the reduced carbohydrate composition of Gray *et al.* In addition, McCabe lists many possible polyols to be used in his invention (see col. 5, line 66 through col. 6, line 2), but neither states that palatinose is preferable nor discloses any advantage of palatinose over the other

polyols. Once again, a skilled artisan would have had no motivation to use the palatinose briefly mentioned by McCabe in the enteral formulation taught by Gray *et al.*

It has been well established in the patent law that the mere fact that the purported prior art could have been modified or applied in some manner to yield an applicant's invention does not make the modification or application obvious unless the prior art suggested the desirability of the modification. In re Gordon, 221 USPQ 1125, 1127 (Fed. Cir. 1984). Moreover, as expressed by the CAFC, to support a §103 rejection, "[b]oth the suggestion and the expectation of success must be founded in the prior art ..." In re Dow Chemical Co. 5 USPQ 2d 1529, 1531 (Fed. Cir. 1988). While the claimed invention requires palatinose be used as a carbohydrate, McCabe never suggested the desirability of using palatinose as a carbohydrate in any composition, including the formulation of Gray *et al.* Additionally, there is nothing in the McCabe reference that would lead a skilled artisan to expect success when using palatinose in an enteral formulation used for treating intensive care patients, as in the composition taught by Gray *et al.* An assertion of obviousness without the required suggestion or expectation of success in the prior art is tantamount to using applicant's disclosure to reconstruct the prior art to arrive at the subject invention. Hindsight reconstruction of the prior art cannot support a §103 rejection, as was specifically recognized by the CCPA in In re Spinnoble, 56CCPA 823, 160 USPQ 237, 243 (1969).

The Examiner asserts that it would have been obvious to one of ordinary skill in the art to modify the protein source of Gray *et al.* by using the enzymatic hydrolysate of whey protein isolate (WPI) disclosed by Davis *et al.* However, the Davis patent pertains to the production of angiotensin converting enzyme (ACE) inhibitors for their antihypertensive properties. This is a completely different purpose than that of the Gray patent. Gray *et al.* do not suggest any necessity of treatment of hypertension, and Davis *et al.* do not teach any necessity for treating trauma, burn, or post-surgery patients.

Thus, the applicants respectfully submit that there is no motivation to combine the cited references to arrive at the claimed invention. See Interconnect Planning Corp. v. Feil, 774 F.2d 1132, 1143, 227 USPQ 543, 551 (Fed. Cir. 1985) ("When prior art references require selective combination by the court to render obvious a subsequent invention, there must be some reason for

the combination other than the hindsight gleaned from the invention itself.”). “The mere fact that elements of [an invention] may be found in various [references] does not necessarily negate invention.” In re McKenna, 203 F.2d 717, 721, 97 USPQ 348, 351 (CCPA 1953). Additionally, the predecessor of the Federal Circuit has opined, “[i]n determining the propriety of the Patent Office case for obviousness in the first instance, it is necessary to ascertain whether or not the reference teachings would appear to be sufficient for one of ordinary skill in the relevant art having the reference before him to make the proposed substitution, combination, or other modification.” In re Linter, 458 F.2d 1013, 1016, 173 USPQ 560, 562 (CCPA 1972). When a rejection depends on a combination of prior art references, there must be some teaching, suggestion, or motivation to combine the references. See In re Geiger, 815 F.2d 686, 688, 2 USPQ2d 1276, 1278 (Fed. Cir. 1987). Therefore, “[w]hen determining the patentability of a claimed invention which combines two known elements, ‘the question is whether there is something in the prior art as a whole to suggest the desirability, and thus the obviousness, of making the combination.’” See In re Beattie, 974 F.2d 1309, 1311-12, 24 USPQ2d 1040, 1042 (Fed. Cir. 1992) (quoting Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co., 730 F.2d 1452, 1462, 221 USPQ 481, 488 (Fed. Cir. 1984)). Finally, the mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. In re Mills, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990).

Fritsche *et al.* teach a hypoallergenic composition containing tolerogenic peptides. This reference also has a completely different purpose than the Gray patent, the McCabe patent, the Davis patent, and the current invention. Thus, Fritsche *et al.* do not provide the missing motivation or expectation of success to the combination of the Gray, McCabe, and Davis references.

As noted above, there would be no motivation to modify the teachings of the cited references in order to arrive at the advantageous compositions and methods of the current applicants. Accordingly, the applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §103(a) based on Grey *et al.* in view of McCabe and Davis *et al.* as evidenced by Fritsche *et al.*

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Claims 4, 5, 12, and 13 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Grey *et al.* (U.S. Patent No. 5,714,472) in view of McCabe (U.S. Patent No. 6,830,766) and Siegenthaler (*The Potential Value of Cultured Dairy Products for Child Nutrition*, abstract). The applicants respectfully traverse this ground of rejection because the combination of references does not teach or suggest the claimed compositions and methods.

The lack of motivation and lack of expectation of success for the combination of the Gray and McCabe patents has been discussed above. Siegenthaler teaches the value of cultured dairy products for children. This reference does not provide any connection between the teachings of Gray *et al.* and McCabe and, thus, does not remedy the deficiencies of the combination. Additionally, the applicants respectfully disagree with the Examiner's assertion that one of ordinary skill in the art would have found it obvious to use a product targeted at the digestive tract of a child in a composition targeted at patients with severe trauma or liver disease. Although both digestive systems may be suboptimal, a skilled artisan would not necessarily assume that the digestive tract of a healthy child would be similar to that of an adult or child with severe trauma or liver disease. Therefore, there is no suggestion to combine the teachings of Gray *et al.*, McCabe, and Siegenthaler.

As noted above, the mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990). Accordingly, the applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §103(a) based on Gray *et al.* in view of McCabe and Siegenthaler.

Claim 1-17 have been provisionally rejected on the ground of nonstatutory obviousness-type double patenting, as being unpatentable over claims 1-36 of copending Application No. 10/487,237. The applicants would like to defer substantive response to this rejection until allowable subject matter has been established in the current application or until the copending application has matured into a patent.

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In view of the foregoing remarks and the amendment above, the applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

The applicants also invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephone interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



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